

**FEDERAL ADVISORY COMMITTEE (FAC)  
MEMBERSHIP BALANCE PLAN**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES/OFFICE OF THE  
SECRETARY/OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH**

**(1) FEDERAL ADVISORY COMMITTEE NAME**

*State the legal of the FAC*

Advisory Committee on Blood and Tissue Safety and Availability

**(2) AUTHORITY**

*Identify the authority for establishing the FAC*

42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Advisory Committee on Blood and Tissue Safety and Availability (the Committee or ACBTSA) is a discretionary federal advisory committee.

**(3) MISSION/FUNCTION**

*Describe the mission/function of the FAC*

The Secretary of Health and Human Services has been given responsibility under Sections 301, 351, and 361 of the Public Health Service Act, as amended (42 U.S.C. 241, 262, 264), and various provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) for issuing and enforcing regulations concerning the collection, preparation, and distribution of blood, blood products, tissues and organs; for issuing and enforcing regulations related to the transmission of communicable diseases; and for carrying out research in health fields including diseases involving these products. The ACBTSA advises, assists, consults with, and makes policy recommendations to the Secretary, through the Assistant Secretary for Health, regarding these broad responsibilities related to the safety of blood, blood products, organs and tissues. For solid organs and blood stem cells, the Committee's work is limited to policy issues related to donor derived infectious disease complications of transplantation. The Committee provides advice on a range of policy issues to include (1) identification of public health issues through surveillance of blood and tissue safety issues with national biovigilance data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical and the legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors, e.g. product cost and supply on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues.

The need for this Committee is solely advisory in nature.

#### **(4) POINTS OF VIEW**

*Based on understanding the purpose of the FAC,*

- (a) describe the process that will be used to ensure the committee is balanced, and identify the categories (e.g., individual expertise or represented interests) from which candidates will be considered;*
- (b) consider identifying an anticipated relative distribution of candidates across the categories; and*
- (c) explain how a determination was made to appoint any individuals as Special Government Employees or Representatives members*

The ACBTSA consists of not more than 23 voting members who represent a diverse group of patient advocates, subject matter experts, and health professionals. One or more of the voting members will be selected to serve as Chair, with an option for Vice Chair or Co-Chairs. The Committee is composed of 14 public members, who are classified as special Government employees (SGEs), and 9 voting representative members who are designated to serve by the blood, tissue and organ professional organizations and/or business sectors. The public voting members are selected from state and local organizations, patient advocacy groups, provider organizations, academic researchers, ethicists, physicians, surgeons, scientists, risk communication experts, consumer advocates, and from among communities of persons who are frequent recipients of blood or blood products or who have received tissues or organs. The official representative members are selected from the AABB, American Association of Tissue Banks (AATB), the Eye Bank Association of America, the Association of Organ Procurement Organizations (AOPO), and one of either the American National Red Cross (ARC) or America's Blood Centers (ABC) on a rotating basis. The Committee composition can include additional representation from either the plasma protein fraction community or a trade organization; a manufacturer of blood, plasma, or other tissue/organ test kits; a manufacturer of blood, plasma, or other tissue/organ equipment; a major hospital organization or a major hospital accreditation organization. When more than one company produces a specified product or process, representatives from those companies will rotate on the same schedule as public members.

The official representative members provide the viewpoints of their respective organizations in the private/business sectors to ensure that the Committee properly addresses the broad range of issues and/or concerns that impact this important public health topic.

The Committee structure also includes nine non-voting *ex-officio* members to represent the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services; the Food and Drug Administration for which representation will be provided by the Office of Blood Research and Review (OBRR) and the Office of Cellular, Tissue and Gene Therapies (OCTGT); the Health Resources and Services Administration, which includes representation from the Chair of the Advisory Committee on Organ Transplantation (ACOT); the National Institutes of Health (NIH) for which representation will be provided by the National Heart, Lung, and Blood Institute and the NIH Clinical Center; the Department of Defense; and the Department of Veterans Affairs. Other federal departments/agencies will be invited to participate as non-voting *ex-officio* members, as the Secretary or designee deem necessary, to effectively carry out the Committee's function.

#### **(5) OTHER BALANCE FACTORS**

*List any other factors your agency identifies as important in achieving a balanced FAC.*

Every effort is made to ensure that the Committee membership is fairly balanced in terms of points of view represented and the Committee's function. Consideration is given to ensure that there is a broad representation of geographic areas, gender, race, ethnicity, and disability.

## **(6) CANDIDATE IDENTIFICATION PROCESS**

*Summarize the process intended to be used to identify candidates for the FAC, key resources expected to be tapped to identify candidates and the key persons (by position, not name) who will evaluate FAC balance. The summary should:*

- (a) describe the process;*
- (b) identify the agency key staff involved (by position, not name);*
- (c) briefly describe how FAC vacancies, if any, will be handled by the agency; and*
- (d) state the membership term limit of FAC members, if applicable.*

A notice is published in the *Federal Register* to solicit applications from individuals who are interested in being considered for appointment to the Committee. The applications received in response to the solicitation are reviewed by appropriate staff in the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), which is a program office within Office of the Assistant Secretary for Health in the Department of Health and Human Services (HHS). OHAIDP has responsibility for providing management support for activities of the ACBTSA. Qualified candidates are selected from this review. The names and pertinent information on the qualified candidates are submitted to the HHS Assistant Secretary for Health to review and give approval for information on the selected candidates to be forwarded in a draft nomination request to the HHS Committee Management Office for the established procedure to be followed. The draft nomination request is forwarded to the HHS Committee Management Office for subsequent review and vetting. The draft nomination request is reviewed by the HHS White House Liaison, Chief of Staff, and other senior level officials in Immediate Office of the Secretary for a determination to be made about the qualifications of the selected candidates to be nominated for appointment. If it is approved for the selected candidates to be nominated for appointment to the Committee, then the formal nomination request to the Secretary is prepared for the necessary action to be taken. Individuals are invited to serve as Committee members for overlapping terms of up to four years. Terms of more than two years are contingent upon renewal of the Committee's charter by appropriate action prior to its expiration. A member may serve no more than 180 days after the expiration of the member's term if a successor has not taken office. If a vacancy occurs, then the applications received in response to the solicitation will be reviewed again to identify a qualified candidate to fill the vacant position. If no qualified candidate can be identified from this review, then information about the vacant position will be widely disseminated to organizations in the public and private sectors which have an interest and/or involvement in blood, blood products, and tissue safety and availability in an effort to locate potential candidates who are qualified to be considered for nomination and appointment to the Committee.

## **(7) SUBCOMMITTEE BALANCE**

*Subcommittees subject to FACA\* should either state that the process for determining FAC member balance on subcommittees is the same as the process for the parent FAC, or describe how it is different.*

*\*This is relevant to those agencies that require their subcommittees to follow all FACA requirements.*

The process that will be used to determine the appropriate balance for membership on the parent committee is used for any subcommittee that is established to assist the ACBTSA.

## **(8) OTHER**

*Provide any additional information that supports the balance of the FAC.*

Not applicable

## **(9) DATE PREPARED/UPDATED**

*Insert the actual date the Membership Balance Plan was initially prepared, along with the date(s) the Plan is updated.*

Prepared: 08/02/2012; Updated: 08/28/2014, 09/14/2016